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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,674	08/09/2001	Suzanne Cory	11686A	3390

7590 04/27/2005

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400 Garden City Plaza
Garden City, NY 11530

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,674

Applicant(s)

CORY ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/31/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 01/01/01 has been acknowledged.
Claims 1-5 and 11-20 are canceled.
Claims 21-22 are newly filed.
Claim 6 is amended.
Claims 6-10 and 21-22 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

The finality of the last Office action is withdrawn in view of new grounds of rejection below.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The amendment filed on 05/06/04 modified the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9, which are not supported by priority documents US 09/155,327 and AU PN8965.

The applicant states that "*The attached substitute Sequence Listing is identical to the Sequence Listing filed with the Preliminary Amendment on August 9, 2002, **with the exception** that SEQ ID NO: 6 and SEQ ID NO: 8 in the attached Sequence Listing are identical to those as disclosed in the instant application when originally filed in the United States under 35 U.S.C. j371 on March 29, 1999*" (response 5/6/04 page 4).

However, the applicant fails to disclose wherein the specification there is support for newly introduced subject matter that introduces SEQ ID NO: 7 and SEQ ID NO:9 as human and mouse bcl-w proteins.

The specification discloses that: "Human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9. The respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively". see spec. page 4, lines 8-10). However the amino acid sequences encoded by the nucleotide sequences of SEQ ID NO:6 and SEQ ID NO:8 do not match the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9 respectively in view of the amendment filed on 05/06/04. Therefore the priority date of the instant application regarding the subject matter of SEQ ID NO: 7 and 9 is 05/06/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of instant claims encompasses isolated polypeptides of SEQ ID NO:7 and SEQ ID NO:9. The applicant had filed an amendment on 05/06/004 to correct the amino acid sequences of SEQ ID NO:7 and SEQ ID NO:9. The specification discloses that:

"Human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9. The respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively". see spec. page 4, lines 8-10)

However the amino acid sequences encoded by the nucleotide sequences of SEQ ID NO:6 and SEQ ID NO:8 do not match the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9 respectively in view of the amendment filed on 05/06/04.

For example recently filed sequence listing (05/06/04) contains Val(85) and Ala(135) instead of Leu(85) and Val(135) in the SEQ ID NO:7. Similarly the sequence listing contains Ala(2), Met(126), Glu(146), Glu (158), Ser(169), Val(170), Arg(171), Leu(174) instead of Pro(2), Ile(126), Asp(146), Asp(158), Val(169), Ser(170), Thr(171), Val(172), Val(173) in SEQ ID NO:9. These newly introduced substitutions and/or additions are inconsistent with applicant's disclosure that human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9 wherein the respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively (see spec. page 4, lines 8-10). In addition the applicant fails to disclose wherein the specification there is support for newly introduced subject matter that introduces SEQ ID NO: 7 and SEQ ID NO:9 as human and mouse bcl-w proteins.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

So the subject matter of claim 6 is apparently new matter. No pages or place in the specification was cited to support this amendment. A careful review by the examiner of the specification failed to identify any support for this new limitation. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by AN: Q92843 (BCLW_HUMAN, 1997), see attached PTO sequence search report Apr. 2005).

The cited art teaches an amino acid sequence which matches 100% to the SEQ ID NO:7 of instant application (see attached PTO sequence search report for AN: Q92843 conducted Apr. 2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

Claims 6-10, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by AN: P70345 (BCLW_MOUSE, 1997), see attached PTO sequence search report Apr. 2005).

The cited art teaches an amino acid sequence which matches 100% to the SEQ ID NO:9 of instant application (see attached PTO sequence search report for AN: P70345, conducted Apr. 2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-10, and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Craig et al (US 6812339, 2004).

The cited art teaches a polypeptide sequence comprising 193 amino acids (SEQ ID NO: 10928), which matches 100% to the SEQ ID NO:7 of instant application (see attached PTO sequence search report for US6812339 SEQ ID NO:10928, conducted Apr.2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Sumesh Kaushal
Examiner GAU 1636



**SUMESH KAUSHAL
PATENT EXAMINER**